JUL - 7 2000

K00494

II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company: .....ESPE Dental AG
Street: .....ESPE Platz
ZIP-Code, City: .....D-82229 Seefeld
Federal State: .....Bavaria
Country: .....Germany
Establishment Registration Number 9611385
Contact: .....Dr. Andreas Petermann, Regulatory Affairs
Phone: 011-49-8152-7001395
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Date: .....May 9, 2000

Name of Device

Proprietary Name: .....PROMPT L-POP®
Classification Name: .....Resin Tooth Bonding Agent
Common Name: .....Dental Adhesive

Predicate Device

PROMPT L-POP® by ESPE .....K 992048
(old formula)

Description for the Premarket Notification

PROMPT L-POP® is classified as a Resin Tooth Bonding Agent (21 C.F.R. § 872.3200) because it is a device intended to be painted on the interior of a prepared cavity of a tooth to improve retention of restorative materials (compomer and composite restorative material).

On August 16, 1999 PROMPT L-POP® was 510(k) cleared by the FDA (K 992048). By its photo initiator system PROMPT L-POP® (K 992048) is designed to be cured with halogen curing lights. Recently, some new types of curing units entered the market, e.g. plasma arc curing lights. The range of wavelength of these curing

units is very narrow and different to that of halogen curing lights, therefore, sufficient light curing of PROMPT L-POP® is not ensured with the new devices. The current instructions for use leaflet of PROMPT L-POP® contains a hint only to use conventional halogen lights only for curing. However, as the market share of the new curing units increases, particularly in the U.S., it is a demand to redesign PROMPT L-POP® to make it suitable to be cured by plasma lights as well. Based on this knowledge, the photo initiator system of PROMPT L-POP® has been exchanged. The resulting PROMPT L-POP® (new formula) is now well suited to be cured by all kinds of dental curing lights in use.

The limitation in the instructions for use, only to use halogen curing lights will be deleted in the new version which is, in our point of view, a significant labeling change.

Due to the FDA guidance document: "Deciding When to Submit a 510(k) for a Change to an Existing Device" published by the Office of Device Evaluation on January 10, 1997 a new 510(k) has to be submitted for PROMPT L-POP® because the labeling changes affect the indications for use.

However, PROMPT L-POP® (new formula) is similar and substantially equivalent to PROMPT L-POP® (K 992048). To provide evidence for the safety of the device, the material safety data sheets of the components and a toxicological assessment carried out by an independent institute are attached. The effectiveness of PROMPT L-POP® is established by performance data.

The results of safety and effectiveness analysis show that the modified PROMPT L-POP® can be light-cured by all curing units in use and that PROMPT L-POP® is a safe and effective dental adhesive.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2000

Dr. Andreas Petermann
Regulatory Affairs
ESPE Dental AG
ESPE Platz
D-82229 Seefeld,
Bavaria, GERMANY

Re: K001494
Trade Name: Modification to PROMPT L-Pop®
Regulatory Class: II
Product Code: KLE
Dated: May 9, 2000
Received: May 12, 2000

Dear Dr. Petermann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001494

III. STATEMENT OF INDICATIONS FOR USE

Device Name: PROMPT L-POP®

Indications for use:

Bonding between dentin/enamel and composite filling materials.

Bonding between dentin/enamel and compomer filling materials.

Bonding mediator for fissure sealing

Bonding mediator for bracket attachment

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001494